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106TH CONGRESS  
1ST SESSION

# H. R. 1039

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 1999

Mr. SAM JOHNSON of Texas (for himself, Mr. LEVIN, Mr. RAMSTAD, Mr. ENGLISH, Mr. HOUGHTON, Mr. McNULTY, Ms. DUNN, Mr. HULSHOF, Mr. FOLEY, Mr. KLECZKA, Mr. CUNNINGHAM, Mr. LUTHER, Mr. SHOWS, Mr. PRICE of North Carolina, Mr. FROST, Mr. DOOLEY of California, Mr. MEEHAN, Mr. TALENT, Ms. LOFGREN, Mr. SHERMAN, Ms. KAPTUR, Mr. CONYERS, Mr. GOSS, Mr. COBURN, Ms. PRYCE of Ohio, Mr. BENTSEN, Mr. HOSTETTLER, Mr. CROWLEY, Mr. SANDLIN, Mrs. CAPPS, and Mr. PAUL) introduced the following bill; which was referred to the Committee on Ways and Means

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## A BILL

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. CREDIT FOR CLINICAL TESTING RESEARCH EX-**  
 2 **PENSES ATTRIBUTABLE TO CERTAIN QUALI-**  
 3 **FIED ACADEMIC INSTITUTIONS INCLUDING**  
 4 **TEACHING HOSPITALS.**

5 (a) **IN GENERAL.**—Subpart D of part IV of sub-  
 6 chapter A of chapter 1 of the Internal Revenue Code of  
 7 1986 (relating to business related credits) is amended by  
 8 inserting after section 41 the following:

9 **"SEC. 41A. CREDIT FOR MEDICAL INNOVATION EXPENSES.**

10 **"(a) GENERAL RULE.**—For purposes of section 38,  
 11 the medical innovation credit determined under this sec-  
 12 tion for the taxable year shall be an amount equal to 20  
 13 percent of the excess (if any) of—

14 **"(1) the qualified medical innovation expenses**  
 15 **for the taxable year, over**

16 **"(2) the medical innovation base period**  
 17 **amount.**

18 **"(b) QUALIFIED MEDICAL INNOVATION EX-**  
 19 **PENSES.**—For purposes of this section—

20 **"(1) IN GENERAL.**—The term 'qualified medical  
 21 innovation expenses' means the amounts which are  
 22 paid or incurred by the taxpayer during the taxable  
 23 year directly or indirectly to any qualified academic  
 24 institution for clinical testing research activities.

25 **"(2) CLINICAL TESTING RESEARCH ACTIVI-**  
 26 **TIES.**—

1           “(A) IN GENERAL.—The term ‘clinical  
2           testing research activities’ means human clinical  
3           testing conducted at any qualified academic in-  
4           stitution in the development of any product,  
5           which occurs before—

6                   “(i) the date on which an application  
7                   with respect to such product is approved  
8                   under section 505(b), 506, or 507 of the  
9                   Federal Food, Drug, and Cosmetic Act,

10                   “(ii) the date on which a license for  
11                   such product is issued under section 351 of  
12                   the Public Health Service Act, or

13                   “(iii) the date classification or ap-  
14                   proval of such product which is a device in-  
15                   tended for human use is given under sec-  
16                   tion 513, 514, or 515 of the Federal Food,  
17                   Drug, and Cosmetic Act.

18           “(B) PRODUCT.—The term ‘product’  
19           means any drug, biologic, or medical device.

20           “(3) QUALIFIED ACADEMIC INSTITUTION.—The  
21           term ‘qualified academic institution’ means any of  
22           the following institutions:

23                   “(A) EDUCATIONAL INSTITUTION.—A  
24                   qualified organization described in section  
25                   170(b)(1)(A)(iii) which is owned or affiliated

1 with an institution of higher education as de-  
2 scribed in section 3304(f).

3 “(B) TEACHING HOSPITAL.—A teaching  
4 hospital which—

5 “(i) is publicly supported or owned by  
6 an organization described in section  
7 501(c)(3), and

8 “(ii) is affiliated with an organization  
9 meeting the requirements of subparagraph  
10 (A).

11 “(C) FOUNDATION.—A medical research  
12 organization described in section 501(c)(3)  
13 (other than a private foundation) which is affili-  
14 ated with, or owned by—

15 “(i) an organization meeting the re-  
16 quirements of subparagraph (A), or

17 “(ii) a teaching hospital meeting the  
18 requirements of subparagraph (B).

19 “(D) CHARITABLE RESEARCH HOS-  
20 PITAL.—A hospital that is designated as a can-  
21 cer center by the National Cancer Institute.

22 “(4) EXCLUSION FOR AMOUNTS FUNDED BY  
23 GRANTS, ETC.—The term ‘qualified medical innova-  
24 tion expenses’ shall not include any amount to the  
25 extent such amount is funded by any grant, con-

1       tract, or otherwise by another person (or any gov-  
2       ernmental entity).

3       “(c) MEDICAL INNOVATION BASE PERIOD  
4 AMOUNT.—For purposes of this section, the term ‘medical  
5 innovation base period amount’ means the average annual  
6 qualified medical innovation expenses paid by the taxpayer  
7 during the 3-taxable year period ending with the taxable  
8 year immediately preceding the first taxable year of the  
9 taxpayer beginning after December 31, 1998.

10      “(d) SPECIAL RULES.—

11           “(1) LIMITATION ON FOREIGN TESTING.—No  
12 credit shall be allowed under this section with re-  
13 spect to any clinical testing research activities con-  
14 ducted outside the United States.

15           “(2) CERTAIN RULES MADE APPLICABLE.—  
16 Rules similar to the rules of subsections (f) and (g)  
17 of section 41 shall apply for purposes of this section.

18           “(3) ELECTION.—This section shall apply to  
19 any taxpayer for any taxable year only if such tax-  
20 payer elects to have this section apply for such tax-  
21 able year.

22           “(4) COORDINATION WITH CREDIT FOR IN-  
23 CREASING RESEARCH EXPENDITURES AND WITH  
24 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER-  
25 TAIN DRUGS FOR RARE DISEASES.—Any qualified

1       medical innovation expense for a taxable year to  
2       which an election under this section applies shall not  
3       be taken into account for purposes of determining  
4       the credit allowable under section 41 or 45C for  
5       such taxable year.

6       “(e) TERMINATION.—This section shall not apply to  
7       any expense paid or incurred after the date specified in  
8       section 41(h)(1)(B).”.

9       (b) CREDIT TO BE PART OF GENERAL BUSINESS  
10      CREDIT.—

11           (1) IN GENERAL.—Section 38(b) of such Code  
12      (relating to current year business credits) is amend-  
13      ed by striking “plus” at the end of paragraph (11),  
14      by striking the period at the end of paragraph (12)  
15      and inserting “, plus”, and by adding at the end the  
16      following:

17           “(13) the medical innovation expenses credit  
18      determined under section 41A(a).”.

19           (2) TRANSITION RULE.—Section 39(d) of such  
20      Code is amended by adding at the end the following  
21      new paragraph:

22           “(9) NO CARRYBACK OF SECTION 41A CREDIT  
23      BEFORE ENACTMENT.—No portion of the unused  
24      business credit for any taxable year which is attrib-  
25      utable to the medical innovation credit determined

1 under section 41A may be carried back to a taxable  
2 year beginning before January 1, 1999.”

3 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of  
4 such Code is amended by adding at the end the following  
5 new subsection:

6 “(d) CREDIT FOR INCREASING MEDICAL INNOVA-  
7 TION EXPENSES.—

8 “(1) IN GENERAL.—No deduction shall be al-  
9 lowed for that portion of the qualified medical inno-  
10 vation expenses (as defined in section 41A(b)) other-  
11 wise allowable as a deduction for the taxable year  
12 which is equal to the amount of the credit deter-  
13 mined for such taxable year under section 41A(a).

14 “(2) CERTAIN RULES TO APPLY.—Rules similar  
15 to the rules of paragraphs (2), (3), and (4) of sub-  
16 section (c) shall apply for purposes of this sub-  
17 section.”

18 (d) DEDUCTION FOR UNUSED PORTION OF CRED-  
19 IT.—Section 196(c) of such Code (defining qualified busi-  
20 ness credits) is amended by redesignating paragraphs (5)  
21 through (8) as paragraphs (6) through (9), respectively,  
22 and by inserting after paragraph (4) the following new  
23 paragraph:

24 “(5) the medical innovation expenses credit de-  
25 termined under section 41A(a) (other than such

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